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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,658	04/11/2001	Blake Pepinsky	0689-514 (A065 US)	2157

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EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/832,658	Pepinsky et al.
Examiner	**Art Unit**
Prema Mertz	1646

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *May 21, 2002* .

2a) [ ] This action is **FINAL**. 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *1-40* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) [ ] Claim(s) _____ is/are allowed.

6) [ ] Claim(s) _____ is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [X] Claims *1-40* are subject to restriction and/or election requirement.

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are a) [ ] accepted or b) [ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____ .
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [X] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) [ ] The translation of the foreign language provisional application has been received.

15) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) [ ] Notice of References Cited (PTO-892)	4) [ ] Interview Summary (PTO-413) Paper No(s).
2) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) [ ] Notice of Informal Patent Application (PTO-152)
3) [ ] Information Disclosure Statement(s) (PTO-1449) Paper No(s).	6) [ ] Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups I-15. Claims 1-24, are drawn to a composition comprising a mutein of IFN-β coupled to a nonnaturally-occurring polymer, said mutein being either A1, A2, AB1, AB2, AB3, B1, B2, C1, C2, CD1, CD2, D, DE1, DE2, E, classified in Class 424, subclass 85.4.

Groups 16-30. Claims 25-40, are drawn to a method of treatment by administering the mutein of IFN-β coupled to a nonnaturally-occurring polymer, said mutein being either A1, A2, AB1, AB2, AB3, B1, B2, C1, C2, CD1, CD2, D, DE1, DE2, E, classified in Class 424, subclass 85.2.

Should any of Groups I-15 be elected, Applicant is required to select one polypeptide (one amino acid sequence). Any change of amino acid residues at any one or more positions in the polypeptide sequence is considered, absent factual data to the contrary, a distinct polypeptide. Once one polypeptide sequence is selected, all other sequences will be withdrawn from consideration.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-15 are independent and distinct, each from the other, because each of the polypeptides are materially different products which are structurally and chemically different, capable of separate manufacture and use. The products in the different Groups are physically and chemically distinct from each other, and if patentable would support separate patents. Distinctness is further shown because a search of one of the polypeptides would not reveal art pertinent to the other and

each of these products can be made and used without any one or more of the other products. Separate searches would be required for searching each of the polypeptide products eg. a search of the literature for the polypeptide A1 would not necessarily reveal art for the polypeptides A2, AB1, AB2, AB3, B1, B2, C1, C2, CD1, CD2, D, DE1, DE2. Therefore, each of the polypeptides are not related and are properly restrictable in accordance with MPEP.. § 806.04 and MPEP.. § 808.01.

Inventions 1-15 and 16-30 are related as products and processes of use, respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case each of the products of inventions I-15 can also be used as antigens in the production of specific antibodies or in immunochromatography, in addition to the method of treatment as recited. Inventions 16-30 are independent and distinct, each from the other, because the methods are practiced with materially different products which are structurally and chemically different, the novelty of the inventions lying in the products being administered and not the processes. The only feature in common in the instant inventions is "the method of treatment with the mutein of IFN-β coupled to a nonnaturally-occurring polymer", said mutein being either A1, A2, AB1, AB2, AB3, B1, B2, C1, C2, CD1, CD2, D, DE1, DE2, E", which does not constitute the special technical feature lacking from the prior art because this method can be used with a composition other than the instant products such as unmodified IFN-β. Distinctness is further shown because each of these products in each method can be made and used without any one or more of the other products. The

products in the different Groups are physically, chemically and biologically distinct from each other, and if patentable would support separate patents. Furthermore, separate search terms would be required for searching the literature, eg. a search of the literature for an association of mutein A1 with treatment would not necessarily reveal art for an association of muteins AB3, C1, C2 or CD2 with treatment. Similarly, a search of the literature with any of muteins AB2, B1 or B2 would not necessarily reveal art for an association of A1 with treatment.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP... § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP.. § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
June 4, 2002